NIOSH Science Blog

N95 Respirators and Surgical Masks

October 14, 2009 by Lisa Brosseau, ScD, and Roland Berry Ann

Please visit our new blogs Respiratory Protection During Outbreaks: Respirators versus Surgical Masks and Proper N95 Respirator Use for Respiratory Protection Preparedness for the most up-to-date information.

With the advent of a novel H1N1 influenza outbreak in spring 2009 and the expectation of a second wave during the 2009–2010 flu season, there has been considerable interest in the use of surgical masks (facemasks) and respirators as infection control measures. Although their appearance is often similar, respirators are designed and engineered for distinctly different functions than surgical masks. The amount of exposure reduction offered by respirators and surgical masks differs. The National Institute for Occupational Safety and Health (NIOSH) and the Centers for Disease Control and Prevention (CDC) recommend the use of a NIOSH-certified N95 or better respirator for the protection of healthcare workers who come in direct contact with patients with H1N1.

The CDC guidance can be found in Interim Guidance on Infection Control Measures for 2009 H1N1 Influenza in Healthcare Settings. In September 2009 the Institute of Medicine released a report "Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A" that also recommends N95 respirators for the protection of healthcare workers from H1N1. This blog examines the scientific principles behind the design and performance of surgical masks and respirators. Although these principles apply to all particulate respirators, the discussion presented in this article is focused on the most frequently used respirator in healthcare settings, the N95 filtering facepiece respirator (FFR).

Evolution of Respiratory Protection against Particulate Exposures

Early surgical masks were constructed from layers of cotton gauze. They were first worn by surgery staff in the early 1900s to prevent contamination of open surgical wounds. With time their design, function, and use have expanded. Today surgical masks are worn in a wide range of healthcare settings to protect patients from the wearers' respiratory emissions. A surgical mask is a loose-fitting, disposable device that prevents the release of potential contaminants from the user into their immediate environment. In the U.S., surgical masks are cleared for marketing by the U.S. Food and Drug Administration (FDA). They may be labeled as surgical, laser, isolation, dental, or medical procedure masks. They may come with or without a face shield. Since OSHA issued the Bloodborne Pathogens Standard (29 CFR 1910.1030) in 1991, surgical masks have been recommended as part of universal precautions to protect the wearer from direct splashes and sprays of infectious blood or body fluids. (The FDA offers further information on surgical masks.)

The first modern respirators were also developed in the early 1900s. The impetus for their development derived from the

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particles, typically within a wide range of sizes (<1 to >100 μm) over a range of airflow (approximately 10 to 100 L/min).

Second, leakage must be prevented at the boundary of the facepiece and the face. However, it is not possible to assure the latter—good face seal performance—without first ensuring a well-functioning filter.

Filter Performance

The filters used in modern surgical masks and respirators are considered "fibrous" in nature—constructed from flat, nonwoven mats of fine fibers. Fiber diameter, porosity (the ratio of open space to fibers) and filter thickness all play a role in how well a filter collects particles. In all fibrous filters, three "mechanical" collection mechanisms operate to capture particles: inertial impaction, interception, and diffusion. Inertial impaction and interception are the mechanisms responsible for collecting larger particles, while diffusion is the mechanism responsible for collecting smaller particles. In some fibrous filters constructed from charged fibers, an additional mechanism of electrostatic attraction also operates. This mechanism aids in the collection of both larger and smaller particle sizes. This latter mechanism is very important to filtering facepiece respirator filters that meet the stringent NIOSH filter efficiency and breathing resistance requirements because it enhances particle collection without increasing breathing resistance.

How do filters collect particles?

These capture, or filtration, mechanisms are described as follows:

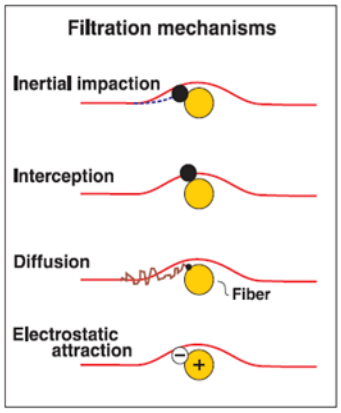

Figure 1: Filtration mechanisms

- **Inertial impaction:** With this mechanism, particles having too much inertia due to size or mass cannot follow the airstream as it is diverted around a filter fiber. This mechanism is responsible for collecting larger particles.
- **Interception:** As particles pass close to a filter fiber, they may be intercepted by the fiber. Again, this mechanism is responsible for collecting larger particles.
- **Diffusion:** Small particles are constantly bombarded by air molecules, which causes them to deviate from the airstream and come into contact with a filter fiber. This mechanism is responsible for collecting smaller particles.
- **Electrostatic attraction:** Oppositely charged particles are attracted to a charged fiber. This collection mechanism does not favor a certain particle size.

In all cases, once a particle comes in contact with a filter fiber, it is removed from the airstream and strongly held by molecular attractive forces. It is very difficult for such particles to be removed once they are collected. As seen in *Figure 2*, there is a particle size at which none of the "mechanical" collection mechanisms (interception, impaction, or diffusion) is particularly effective. This "most penetrating particle size" (MPPS) marks the best point at which to measure filter performance. If the filter demonstrates a high level of performance at the MPPS, then particles both smaller AND larger will be collected with even higher performance.

This is perhaps the most misunderstood aspect of filter performance and bears repeating. Filters do NOT act as sieves. One of the best tests of a filter's performance involves measuring particle collection at its most penetrating particle size, which ensures better performance for larger and smaller particles. Further, the filter's collection efficiency is a function of the size of the particles, and is not dependent on whether they are bioaerosols or inert particles.

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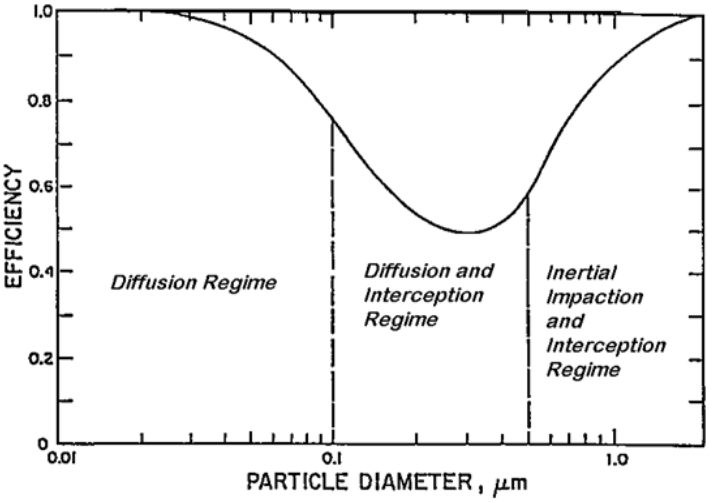

Figure 2: Filter efficiency versus particle diameter

How are surgical masks and respirator filters tested?

Respirator filters must meet stringent certification tests (42 CFR Part 84) established by NIOSH. The NIOSH tests use what are considered “worst case” parameters, including:

- A sodium chloride (for N-series filters) or a dioctyl phthalate oil (for R- and P-series filters) test aerosol with a mass median aerodynamic diameter particle of about 0.3 µm, which is in the MPPS-range for most filters
- Airflow rate of 85 L/min, which represents a moderately-high work rate
- Conditioning at 85% relative humidity and 38°C for 24 hours prior to testing
- An initial breathing resistance (resistance to airflow) not exceeding 35 mm water column* height pressure and initial exhalation resistance not exceeding 25 mm water column height pressure
- A charge-neutralized aerosol
- Aerosol loading conducted to a minimum of 200 mg, which represents a very high workplace exposure
- The filter efficiency cannot fall below the certification class level at any time during the NIOSH certification tests

* Millimeters (mm) of water column is a unit for pressure measurement of small pressure differences. It is defined as the pressure exerted by a column of water of 1 millimeter in height at defined conditions, for example 39°F (4°C) at standard gravity.

As a result of these stringent performance parameters, fiber diameters, porosity, and filter thicknesses of all particulate filters used in NIOSH-certified respirators, including N95s, are designed and engineered to provide very high levels of particle collection efficiencies at their MPPS.

Manufacturers of surgical masks, on the other hand, must demonstrate that their product is at least as good as a mask

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parameters for surgical masks are less stringent than those required for filters used in NIOSH-certified respirators, the fiber

diameters, porosity, and filter thicknesses found in surgical masks are designed with significantly lower levels of particle collection efficiencies at their MPPS.

How do surgical mask and respirator filters perform?

Respirator filters that collect at least 95% of the challenge aerosol are given a 95 rating. Those that collect at least 99% receive a “99” rating. And those that collect at least 99.97% (essentially 100%) receive a “100” rating. Respirator filters are rated as N, R, or P for their level of protection against oil aerosols. This rating is important in industry because some industrial oils can remove electrostatic charges from the filter media, thereby degrading (reducing) the filter efficiency performance. Respirators are rated “N” if they are not resistant to oil, “R” if somewhat resistant to oil, and “P” if strongly resistant (oil proof). Thus, there are nine types of particulate respirator filters:

- N95, N-99, and N-100
- R-95, R-99, and R-100
- P-95, P-99, and P-100

Respirator filters are tested by NIOSH at the time of application and periodically afterward to ensure that they continue to meet the certification test criteria. The FDA does not perform an independent evaluation of surgical mask filter performance, nor does it publish manufacturers’ test results. In many cases it is difficult to find information about the filter test results for FDA-cleared surgical masks. The class of FDA-cleared surgical masks known as Surgical N95 Respirators is the one clear exception to this uncertainty of filter performance. This is the only type of surgical mask that includes evaluation to the stringent NIOSH standards. All members of this class of surgical masks have been approved by NIOSH as N95 respirators prior to their clearance by the FDA as surgical masks. The FDA, in part, accepts the NIOSH filter efficiency and breathing resistance test results as exceeding the usual surgical mask requirements.

In studies comparing the performance of surgical mask filters using a standardized airflow, filter performance has been shown to be highly variable. Collection efficiency of surgical mask filters can range from less than 10% to nearly 90% for different manufacturers’ masks when measured using the test parameters for NIOSH certification. Published results on the FDA-required tests (if available) are not predictive of their performance in these studies.

It is important to keep in mind that overall performance of any facepiece for particulate filtering depends, first, on good filter performance. A facepiece or mask that fits well to the face but has a poor filter will not be able to provide a high level of protection.

Respirator and Surgical Mask Fit

Because respirator filters must meet stringent certification requirements, they will always demonstrate a very high level of collection efficiency for the broad range of aerosols encountered in workplaces. There has been some recent concern that respirator filters will not collect nano-sized particles, but research has demonstrated that such particles are collected with efficiencies that meet NIOSH standards. This is not surprising, because NIOSH tests employ small, charge-neutralized, relatively monodisperse aerosol particles and a high airflow.

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respirators inherently offer less protection than positive pressure respirators, because inward leakage occurs more easily in

the former.

The facepiece design is also very important—some designs fit on the face better than others. It is more difficult to fit a half-facepiece respirator (one that covers the mouth and nose only) than a full-facepiece respirator (one that also covers the eyes). The nose and chin are the most difficult facial features on which to establish a tight fit. The fit of a hood, helmet or "loose-fitting" facepiece is highly dependent on the specific design and configuration. More details on the different classes of respirators and their levels of protection, can be found on the NIOSH respirator topic page and the OSHA Respiratory Protection Standard

Because fit is so important, NIOSH recommends and OSHA requires that each respirator wearer receive an initial fit test and annual fit tests thereafter. It is not possible to predict how well a respirator will fit on a particular face, even for respirators that fit well on a broad range of facial sizes. The FDA does not recommend or require any test of fit for surgical masks. A very limited number of published studies are available on this aspect of surgical mask performance. Three clinical studies conducted in the 1980s and 90s found no difference in surgical infection rates when staff did not wear surgical masks.[1], [2], [3]

A recent laboratory study of five surgical masks with "good" filters found that 80–100% of subjects failed an OSHA-accepted qualitative fit test using Bitrex (a bitter tasting aerosol) and quantitative fit factors ranged from 4–8 (12–25% leakage) using a TSI Portacount.[4] In contrast, the least protective type of respirator (negative pressure half mask) must have a fit factor (outside particle concentration divided by inside concentration) of at least 100 (1% leakage).

NIOSH would like to hear from you regarding your experiences working with NIOSH-approved respirators and FDA-cleared surgical masks. For example, are there user needs for increased comfort and wearability that NIOSH could help address? Do users feel that exhalation valves on disposable, filtering facepiece impact the wearer's ability to successfully perform a user seal check? Are there certain aspects of filtering facepiece respirator design that could be improved for better fit? How would you compare the comfort and wearability of surgical masks and filtering facepiece respirators?

Additionally, the NIOSH Respirator Trusted-Source Information Page can help users identify NIOSH-approved respirators and learn how to use and obtain these products.

Dr. Brosseau is a faculty member in the University of Minnesota's School of Public Health whose research focuses on the performance of respiratory protection, measurement of aerosols, and assessment of workplace exposures to hazardous materials and wastes. Dr. Brosseau was Chair of the ACGIH Threshold Limit Values for Chemical Substances Committee from 1995–2005 and is currently Vice Chair Elect of ACGIH.

Mr. Berry Ann is the Deputy Director of the NIOSH National Personal Protective Technology Laboratory. He has more than 15 years experience working in respirator certification and PPT issues at NIOSH.

References

1. Orr, N. W. 1981. Is a mask necessary in the operating theatre? Annals of the Royal College of Surgeons of England 63, (6) (Nov): 390-2.
2. Mitchell, N. J., and S. Hunt. 1991. Surgical face masks in modern operating rooms—a costly and unnecessary ritual? The Journal of Hospital Infection 18, (3) (Jul): 239-42.

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October 14, 2009 by Lisa Brosseau, ScD, and Roland Berry Ann
COVID-19, Healthcare, Infectious Disease Resources, Personal Protective Equipment, Respirators, Respiratory Health, Women
respirator

163 comments on “N95 Respirators and Surgical Masks”

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From training and experience using both filtering face masks and powered air purifying hoods in controled medical settings and austere environments, I have come to some conclusions. Sometimes one type will work better than the other.

FFMs have the advantage of portability and easy access. Use in situations where noise or commotion exists, I suppose both types of protection will limit it’s wearer being heard, but wearing a FFM, the wearer’s face and therefor facial expression is hidden. This can be scary for children being treated. I suppose PAPRs, while allowing facial recognition, may be just as alarming to patients.

In hot or humid conditions FFMs can degrade quickly and become hard to breath through. I find vented ones last longer and are easier to breath through. These are more expensive than non-vented FFMs so find their availability scarce.

In later environment PAPRs may last longer, be much easier to breath with, and be cooler, but also cost more.

Will Hill RN

Influenza virus is spread through viral contact with mucous membranes.

This is even stated in the CDC interim guidelines. It is not spread from inhaling respiratory particles as with tuberculosis. You can campare surgical masks to N95 respirators all you want. You are not researching the real issue, protecting the exposed mucous memebranes. The appropriate mask for any influenza or other virus spread via droplet would be a fluid shield or a mask and goggles. It seems to me that the obvious is being over looked.

Presentations made at the IOM meeting in August indicate that influenza transmission is also associated with close range exposure to small particles generated during speaking, coughing, and sneezing (links are included below). The traditional infection control paradigm does not consider this type of exposure. Surgical masks do not provide wearer protection for exposures to small particles (due to poor filtration and fit performance). Respirators are designed to offer such protection.

The following isolation precautions are recommended for healthcare personnel who are in close contact with patients with suspected or confirmed 2009 H1N1 influenza. For the purposes of this document, close contact is defined as working within 6 feet of the patient or entering into a small enclosed airspace shared with the patient (e.g., average

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staff giving care.

The exception is Long Term Care Facilities, which further illustrates that. Colonization of microorganisms is found frequently in catheterized patients and thiose with open skin lesions; and when all patients are treated in a timely manner, that resolves. The source has most often been in staff members using medical equipment jointly. That has resulted in individual purchase by nurses' of their own stethascopes, and more diligent use of disinfectants when another staff member uses theirs.

It is heartening to see the advances in the manufacture of surgical masks/respirators. I'd like to know how much study is happening to compare post-op infection rates with their use, and the earlier ones, without their use.

From a nursing education standpoint, is there any guidelines for fit testing of students for clinical experiences for the N95 masks? Thank you for the feedback-

> The guidelines for fit testing are the same for all respirator users. The American National Standard for Respirator Fit Testing Methods (ANSI Z88.10-2001) is a national consensus standard that provides guidance on how to conduct fit testing of tight fitting respirators (like N95 respirators), and the appropriate methods to use. Additionally, Paragraph (f)(1) of the Occupational Safety and Health Administration (OSHA) Respiratory Protection Standard (29 CFR 1910.134) requires that all tight-fitting respirators be fit tested in accordance with the requirements of the standard, including the fit test methods described in Appendix AMandatory Fit Test Protocols. Either of these references should provide you with the guidelines for fit testing of the students you are seeking.

I am an Infection Preventionist. We know that H1N1 is spread by large droplets as is other influenzas. If it is recommended that HCWs wear N95 respirators to deal with confirmed or suspected H1N1 then I would want to know why this not considered an Airborne disease requiring a neg. pressure room. N95 masks are difficult to come by and require fit testing and education for them to be effective. It is a burden on the hospital to provide this level of protection for a disease that is considered to spread by large droplets and contact with the secretions. I like many other Infection Preventionists do not understand the recommendation for N95 respiratory protection for anything other than those procedures that cause aerosolization of the virus.....seems like over kill.

> The current evidence in support of airborne transmission of influenza has been discussed in a recent Institute of Medicine report, Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A: A Letter Report.
>
> Although there is strong evidence to support airborne transmission across short distances as a potential mode of transmission, there is not evidence to suggest that this agent is able to transmit over long distances (such as through air handling systems) or to cause prolonged airspace contamination. Thus, it differs from agents such as TB. In view of this, CDC guidelines recommend respiratory protection for close contact, defined as a distance of fewer than 6 feet from a patient or entry into a shared airspace equivalent to a typical patient room. Use of negative pressure, airborne infection isolation rooms is only recommended for aerosol-generating procedures (as feasible, since CPR and intubation are noted to be aerosol-generating procedures). The guidelines also recognize the supply issues that many facilities have faced in obtaining disposable N95 respirators and offer a range of practical options for dealing with those shortages.
>
> *[David Weissman is Director of the NIOSH Division of Respiratory Disease Studies]*

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respirator slippage on your face during normal work activities should be brought to the attention of your Respiratory Program Administrator. The use of the current respirator should be re-evaluated, since the protection being provided is likely to be adversely affected with changes to the facepiece-to-face fit as the respirator slips. This assessment needs to be done in the workplace to determine the type and level of respiratory protection required for the exposures and work activities normally encountered. You should contact your Respiratory Program manager to discuss the situation and determine other types of respirators that may be available for your use.

Nurses and other caregivers in our intensive care units found themselves working for extremely long periods of time, caring for very ill patients with confirmed or suspected nH1N1 cases during the late Spring-early Summer period just passed. Not surprisingly, they found the N95's became soggy, affecting fit and comfort. Skin conditions were reported by some, attributed to extended wear. Many developed a preference for the powered air purifying respirator as a result. However, as patient volume and demand for this resource may potentially grow, the PAPR may become a scarce resource, leaving clinicans and other caregivers with challenges in both supply of N95's (we experienced resupply difficulties) and comfort and endurance in providing patient care.

really good

I just want to know, in outpatient settings, without invasive procedures, can a droplet mask be utilized as opposed to the N95 for protection.

This guidance applies to healthcare personnel working in the following settings: acute care hospitals, nursing homes, skilled nursing facilities, physician's offices, urgent care centers, outpatient clinics, and home healthcare agencies. CDC continues to recommend the use of respiratory protection that is at least as protective as a fit-tested disposable N95 respirator for healthcare personnel who are in close contact with patients with suspected or confirmed 2009 H1N1 influenza.

Careful attention to elimination of potential exposures through engineering controls and administrative controls will reduce the need to rely on PPE, including respirators. This is an especially important consideration during the current year, when shortages of respirators have already been reported by many healthcare facilities.

Healthcare facilities will want to use a multi-level approach, called the hierarchy of controls, that includes both administrative controls and engineering controls to eliminate sources of infection and prevent transmission within their facility.

To ensure a comprehensive infection control strategy, healthcare facilities will want to:

◦Vaccinate their workforce with seasonal and 2009 H1N1 vaccines.
◦Keep sick workers at home.
◦Enforce respiratory hygiene and cough etiquette.
◦Enhance hand hygiene compliance.
◦Establish facility access control measures and triage procedures.
◦Manage visitor access and movement within the facility.
◦Control patient placement and transport.
◦Apply isolation precautions.

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worker wearing N95 PPE. The actual 'fitting' of the mask is, in my opinion the least effective aspect of a respiratory program that deals with N95's.

I think a stronger emphasis should be put on the educational portion and leave the 'fit testing' for the rubber seal PPE (SCBA, half/full mask, etc).

Definitely there is more research and work to be done.

What I see is, change those things often,fit was the issue for me, moisture, getting one to last 2-hrs, field dirt, millcleaning, who would know how much still would get by,doing a warm saline rinse,and couphing up what you can.

Don't save, or reuse one, or share one, eye protection is needed for what I was doing too,canister type respirator ok, if you don't bump, and disloge one of your filters, Point to take out is, tools made to help can fail,or not be fit for the task, liability, is your own health at risk.

This study found that the difference in protection between surgical mask and N95 respirators are not statistically significant. What is your opinion regarding this study?
http://jama.ama-assn.org/cgi/content/full/2009.1466

Thank you for your question. Randomized controlled trials such as this one [Loeb et al. Surgical mask vs. N95 respirator for preventing influenza among health care workers. JAMA 2009; 302(17): (doi:10.1001/jama.2009.1466)] are very important for documenting the effectiveness of interventions. This study, the first of its kind, examined the impact of assigning nurses to use surgical masks or N95 respirators. It did not find a statistically significant difference between groups in incidence of developing laboratory changes suggesting influenza infection (50/212 in the surgical mask group vs. 48/210 in the N95 group, p = 0.86). In both groups, most of these laboratory changes represented 4-fold increases in titer of serum anti-influenza antibody over the course of the study (44/212 in the surgical mask group vs. 44/210 in the N95 group).

Because symptomatic disease was rare, the study had limited ability to evaluate the effect of surgical mask vs. N95 respirator on clinically significant disease. However, influenza-like illness tended to be lower in those using N95 respirators (9/212 in the surgical mask group vs. 2/210 in the N95 group, p = 0.06) and fever was significantly less frequent in the N95 group (12/212 in the surgical mask group vs. 2/210 in the N95 group, p = 0.007). Thus, the study findings were not consistent across laboratory outcomes on one hand, and clinical outcomes on the other.

Many nurses in both arms of the study were exposed at home to spouses, roommates, or children with influenza-like illness. It is unclear whether cases of influenza observed in the nurses resulted from work or home exposures.

In summary, this study is an important first step. The authors are to be congratulated for taking on such a difficult problem. However, the study does not definitively resolve the ongoing controversy of when to use surgical masks and when to use respiratory protection to prevent transmission of influenza. More studies are needed with better power to address clinically significant disease as an outcome. Also, as more studies become available, it will be possible to assess coherence of results across multiple studies and even to pool data from multiple studies for meta-analysis. Although difficult, this research continues to be greatly needed.

Echoing Jim's comment (11) above: education is key. In a true crisis, there would be a mask shortage. Experienced users

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alleviate “supply and demand” issues and may assist healthcare providers with choosing alternate respirators when the NIOSH/FDA approved respirators are in short supply or unavailable.

The Interim Guidance on Infection Control Measures for 2009 H1N1 Influenza in Healthcare Settings, Including Protection of Healthcare Personnel recommends isolation precautions that incorporate the use of Standard Precautions as well as respiratory protection for healthcare personnel who are in close contact with patients with suspected or confirmed 2009 H1N1 influenza. CDC continues to recommend the use of respiratory protection that is at least as protective as a fit-tested NIOSH-approved, disposable N95 respirator for these instances. Standard Precautions include the use of gowns along with eye protection for any activity that might generate splashes of respiratory secretions or other infectious material. A faceshield is one form of eye protection that can be used in conjunction with a NIOSH-approved N95 respirator for protection during for splash-generating activities.

The FDA provides guidance to the healthcare industry regarding the difference between a NIOSH-approved and FDA-approved respirator on their website.

A somewhat frivolous question, but seasonal also. Will decorating the N95 masks with colored markers compromise their effectiveness?

NIOSH-approved respirators go through a rigorous testing and certification process. Alterations to a respirator, including decorating with ink or paint, can be detrimental to the respirator’s performance and may void the NIOSH certification.

As #13 commented,
“This study found that the difference in protection between surgical mask and N95 respirators are not statistically significant. What is your opinion regarding this study? http://jama.ama-assn.org/cgi/content/full/2009.1466

I would like to see a response to this as well. I work as a RN in a large acute hospital setting and am being told by my hospitals adm. that we are to use surgical masks – not N95 respirators. This decision was supported when the recent study regarding the difference in protection between surgical masks and N95’s was published in Oct in JAMA. I believe OSHA and CDC are not looking at $ signs when making reccomendations as hospitals are. My feeling is – if hospitals want HCWs to care for infected pts, then they need to step up to the plate and protect those HCWs.

Please respond on the study in question.

Please see the response to #13 above.

Because N 95’s are in short supply, is it possible for the same nurse to re-use the 1860 N 95 3M mask throughout their shift? If so, what is the best way to store the mask-is a sealable plastic bag acceptable or another receptable that would maintain the shape of the mask?

Lisa and Roland say:
In the setting of supply shortages, facilities may need to consider extending the use of each respirator. There are two resources available on the NIOSH web page, NIOSH Safety and Health Topic: Occupational Health Issues Associated with H1N1 Influenza Virus (Swine Flu) (http://www.cdc.gov/niosh/topics/H1N1flu/) that address the possibility of extending the use of respirators similar to the scenario you describe.Questions and Answers about CDC’s Interim Guidance on Infection Control Measures for 2009 H1N1 Influenza in Healthcare Settings, Including Protection of

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Control Measures for 2009 H1N1 Influenza among Healthcare Personnel (http://www.cdc.gov/h1n1flu/guidance/ili-

hcp_qa.htm#reuse) .

If extended use practices are implemented as a means to extend respirator supplies, measures should be taken to reduce contact transmission, including:

◦Discarding disposable N95 respirators following use during aerosol generating procedures.
◦Discarding disposable N95 respirators if contaminated with blood, respiratory secretions, or other bodily fluids from patients.
◦Considering use of a face shield over the disposable N95 respirator to prevent surface contamination.
◦Performing hand hygiene before and after touching the respirator.
If re-use is chosen as a strategy to increase availability of respiratory protection, the following should be considered to minimize risk of transmission:

◦Discard disposable N95 respirators following aerosol-generating procedures.
◦Discard disposable N95 respirators contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
◦Disposable respirators must only be used and re-used by a single wearer.
◦Do not re-use a disposable respirator that is obviously contaminated, damaged or hard to breathe through.
◦Consider use of a face shield over a disposable N95 respirator to prevent surface contamination.
◦Store the respirator in a clean, breathable container such as a paper bag between uses.
◦Avoid touching the inside of the respirator.
Wearer should perform hand hygiene with soap and water or an alcohol-based hand sanitizer before and after touching a used respirator.

A reader of my blog, http://www.oshahealthcareadvisor.com, asks:

"I was an OR nurse for 21 years (temp. retired). It has always been my understanding that a typical surgical mask looses its protective ability when exposed to moisture. This would occur during coughing, sneezing, talking, etc. Many surgical mask users are convinced a mask maintains its patency under most conditions. Can you clarify?"

Surgical masks are not evaluated on their ability to maintain their protective capabilities when exposed to moisture buildup from coughing, sneezing, talking, etc. We are unaware of any published studies that evaluate the loss in protection over time in either experimental or realistic settings.

I have to disagree with this sentence in your otherwise useful blog entry:

A negative pressure respirator will inherently not fit as well as a positive pressure respirator with the same type of facepiece.

Fit is a measure of facepiece to face seal leakage only. All other sources of leakage are assumed to be essentially zero. 'Fit' is measured in the negative pressure mode only. Total inward leakage can be affected by positive vs. negative pressure. 'Fit' is not.

Thank you for your comment. We have edited the sentence to read: "Negative pressure respirators inherently offer less protection than positive pressure respirators, because inward leakage occurs more easily in the former."

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The actions of Health Care Workers (HCW) taking a NIOSH-approved N95 FFR out of its “ready to use package”, inspecting it, donning it, wearing it, doffing it, and disposing it or re-using it, has now gotten the attention of the medical science community regarding efficacy of use in SARS, Avian H5N1, and H1N1 contagion outbreaks. Environmental workers cleaning up spores in congressional offices relied on many types of PPE, one of them being the NIOSH-approved PAPR, to protect their breathing zones, with only sparse use of N95 FFR

NIOSH-approved respirators offering “CBRN protection” have captured years of “best practice science” and user survival techniques into many respirator technology platforms whether they be SCBA, APR, PAPR, APER, or loose fitting PAPR. NIOSH-approved N95, N99, N100, R95, P95, P99, or “P100” filtering facepiece respirators do in fact “stop”-filter-out particle sized contagions along a defined air-pressure boundary, from entering the breathing zone. However the safety of the wearer is more about how trained the wearer is in using the respirator with interfacing PPE; what type of vaccinations the wearer currently has viable in his/her physiology; and what “dose” is actually recieved….than how the respirator technology is actually performing regarding “human face-to-faceblank” total inward leakage (TIL), faceblank and seal slippage, assigned protection factor repeatability data, workplace protection factor data, or proprietary use technology designed to capture the multitude of facial anthropometrics that are evolving in the human species.

If you are symptomatic with H1N1 or any type of biological contagion, stay home, get well, and if available, wear a FDA-cleared surgical mask for your own self preservation and the preservation of your loved ones. If you are a HCW charged, or confident enough, to enter a H1N1 or any other type of biological aerosol contagious patient room, at the minimum wear a FDA-cleared/NIOSH-approved FFR certified to at least a NIOSH-N95 filter series and efficiency level.

Most responders would rather not wear a respirator, but realize that wearing a respirator does in fact reduce their chances of gaining an acute lethal dose, or a chronic lethal/non-lethal handicapping dose. HCW should take heed and look at the “biological species indicators” around the globe and apply best practices that are the most beneficial to the survival of their local “customers/patients/stakeholders/warriors/responders and workers”.

Would someone please comment on the BioMask made by Filligent and the prospects for getting it NIOSH approved and available in the USA?

> The Filligent BioMask is not a NIOSH-approved respirator. To become certified as an approved respirator, the respirator must meet the all minimum requirements of the approval regulations in Title 42 Code of Federal Regulations, Part 84. Full details can be found at the NIOSH respirator website. Seeking NIOSH approval, manufacturing to quality standards, and distribution is the responsibility of the manufacturer.
>
> The NIOSH approval process does not include evaluation of claims of killing or inactivation of germs, viruses, or other biological agents for the prevention of disease. The Food and Drug Administration (FDA) evaluates such product claims and issues clearance to advertise those capabilities for products that are determined to have demonstrated efficacy in the ability to prevent disease. Seeking FDA clearance is the responsibility of the manufacturer.

Thank you, this is a very well considered article – and very helpful to provide to those healthcare workers who do not understand the difference between protection for the patient (mask) and protection for the wearer (respirator).

Would appreciate a future study analysis of appropriate respiratory protection for laser users. Because the FDA allows vendors to market surgical masks as ‘laser masks’…healthcare workers often believe, with a false sense of security, that

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I have heard that there is an “emergency” exception to the fit testing requirment for N95 respirators. Is this true, and if so,

what is the specific authority? What constitutes an emergency for purposes of this exception? Thanks.

No, there is no emergency exception to the fit testing requirement. OSHA recently issued a compliance directive for health care workers. In the OSHA News Release from November 20, 2009, it prescribes: "Where respirators are required to be used, the OSHA Respiratory Protection standard must be followed, including worker training and fit testing. The directive also applies to institutional settings where some workers may have similar exposures, such as schools and correctional facilities." The full text of the News Release and the Directive is available at:

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=16749

Dear colleagues:

As an infection control officer (physician) in a hospital of a poor nation, I am faced with limited supplies of N 95 and even surgical respirators. The hospital where I just started to work was "suddenly" ordered by the Minister of Health to start managing H1N1 patients. It is a 500 bed multi specialty hospital with a huge daily outpatient load. ER and Outpatient layout is not designed completely separate patients who need isolation from the rest of the patients. The only room available as an isolation room in the ER, for example, is two rooms inwards. Patients will inevitably pass by "regular" patients and rooms before being isolated and examined.

I know that so far "air borne" transmission of H1N1 is not believed to occur, but it cannot be totally excluded. Ideally, I believe, everyone in the potential path of an H1N1 patient needs an N 95 respirator, something I cannot provide.

My question is: How can I maximize the use of N 95 respirators and surgical (setting priorities)? If reused, what precautions are needed regarding the N 95 respirator during reuse and storage?

Thank You

Please see the response to comment 18 above.

Is there any FDA approval (510k) necessary for n95 respirators for use by the general public as opposed to operating room personel. (other than Emergency Use Authorization). If so, which brands have such clearance?

FDA approval is not needed for N95 respirators used by the general public or for N95s used by healthcare personnel to reduce exposure to hazardous particulates in a patient care setting. However, N95s are not intended for use in exposure settings where the performance of a surgical mask to maintain a sterile field is required.

I am a nurse working in Alaska in a pressurized fixed wing aircraft. The duration of our patient care time often exceeds 4 hours. During our transports we are frequently exposed to wind, rain, and variable temperatures. I read the comments regarding moisture and effectiveness of N-95 masks with interest. I am also interested to learn more regarding the interface of the mask to the face and impairment of adequate fit. As a male I am curious at what point facial hair growth impacts this seal.

I have two questions:

1. Are you aware of any information regarding the use of PAPRs for healthcare PPE in a pressurized aircraft.

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ensuring adequate mask to face interface for an appropriate seal or do you suggest a PAPR.

Paragraphs (g)(1)(i) and (g)(1)(ii) in OSHA's 29 CFR 1910.134 are intended to ensure that facial hair is prevented from interfering with the facepiece seal or valve function. We are unaware of any interpretive OSHA compliance or NIOSH policies defining a time duration between shaves or length of "stubble" or beard growth that would be prohibited. Although the growth and beard density varies among individuals, generally, a one-day's growth of facial hair is deemed acceptable to avoid interfering with the facepiece's ability to seal to the wearer's face.

I am an Infection Control coordinator at a Rehab hospital. We usually do not admit patients to our hospital with Influenza, but if we would suspect they were symptomatic with ILI, if severe enough they would be sent out to acute care. If they were not severely sick, they would stay, but the therapy would need to be limited, possibly confining them to their rooms.

We discussed our protocol to implement for H1N1 and we are running into issues, i.e., we do not have AIIR nor do we have a respiratory protection program in place. We now are attempting to comply with the new CDC recommendations for use of N95s, but it is very difficult for us, as a rehab, to implement a protocol for the type of services we provide. We do not fit test either. Our psyiatrists have shared with me the JAMA article, and I have several other pieces of literature on this controversy of N95s vs. surgical masks. They think surgical masks will do. I am attempting to create a new policy to add to our pandemic flu policy, but have come to a standstill. I just don't feel comfortable with not following recommendations, but how do you implement these recommendations in a rehab type setting??? Thanks for any advice.

Thank you for your question. We appreciate the challenges that you describe. We also appreciate your desire to protect both your workers and your many fragile rehabilitation patients from transmission of 2009 H1N1 influenza.

In your question, you mention that your rehabilitation hospital does not have airborne infection isolation rooms. This should not be an issue for you, since the CDC guidelines recommend use of such rooms only as possible for aerosol-generating procedures. "As possible" refers to the fact that cardiopulmonary resuscitation and endotracheal intubation are two of the procedures listed in the guidelines as aerosol-generating.

The CDC guidelines do recommend that healthcare personnel in close contact with suspected or confirmed 2009 H1N1 cases use respiratory protection at least as protective against inhalation of small particulate aerosols as disposable N95 respirators. This recommendation does apply to your rehabilitation hospital. Hopefully recommendations provided in the respiratory protection questions and answers documents produced in association with the guidelines will help in implementing the recommendation with as little impact on your operations as possible:

◦Questions and Answers about CDC's Interim Guidance on Infection Control Measures for 2009 H1N1 Influenza in Healthcare Settings, Including Protection of Healthcare Personnel
◦Questions & Answers Regarding Respiratory Protection for Infection Control Measures for 2009 H1N1 Influenza among Healthcare Personnel
Because there is substantial evidence that influenza may be transmitted over short distances by small particulate aerosols, a recent Institute of Medicine report recommended use of N95 respirators in a fashion similar to that recommended in the CDC guidelines. Because surgical masks do not provide protection against small particulate aerosols, the CDC guidelines only recommend their use by healthcare personnel at lower risk from influenza if supply issues make true respiratory protection unavailable. In many cases, personnel can be assigned to a lower risk category 14 days after vaccination for 2009 H1N1 influenza.

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I am hoping someone can help me (a relatively new-be) understand something. The site sattes thate performance

parameters for surgical masks are less stringent than those required for filters used in NIOSH-certified respirators? I don't fully understand this. Is there a difference in what NIOSH is looking for to assign NIOSH-certification vs. what FDA is looking for to get FDA-clearance?

Is an FDA-cleared N95 respirator better than a NIOSH-certified respirator?

Thanks for any help you can provide.

FDA clearance for marketing requires that a new surgical mask demonstrate performance at least as good as that demonstrated by other currently-marketed surgical masks. The FDA pre-marketing notification application suggests that manufacturers address the following aspects of surgical mask performance:

1.fluid resistance
2.filter efficiency
3.differential pressure (pressure drop)
4.comfort
5.flammability
Performance of previously-cleared surgical masks is highly variable in all of these aspects, and equal performance to a lesser-performing mask can be accepted as basis for clearance of a new surgical mask model. See this FDA site for more details.

Manufacturers wishing to obtain FDA clearance for a NIOSH-certified respirator may forgo the filter efficiency and differential pressure tests, as the NIOSH certification requirements exceed the minimum performance of previously-cleared surgical masks in these aspects. In fact, the NIOSH filter efficiency tests are much more rigorous than those suggested by FDA for surgical masks.

Most importantly, however, the FDA tests do not consider one of the most important aspects of good performance, how well the facepiece fits to the face. There is no expectation, therefore, that surgical masks can or will prevent penetration of particles around the facepiece.

Why are there no N95 respirators with exhalations valves which have been FDA-cleared?

NIOSH obtained an opinion on your question from Dr. Sheila Murphey, an Infection Control Medical Officer at the FDA's Center for Devices and Radiologic Health.

FDA clears NIOSH-certified N95 respirators as medical devices under the "Surgical Apparel" regulation (21 CFR 880.4040) so that they can be used in patient care. Such respirators are used in the performance of invasive procedures such as bronchoscopy, difficult intubation, etc as well as in the care of patients with transmissible infections. When worn during an invasive procedure, they need to protect the patient from the healthcare professional's exhalations as well as the reverse.

A NIOSH-certified N95 respirator intended for healthcare use which had an exhalation valve would need a label cautioning against its use in invasive procedures and an additional caution that it should not be worn by anyone with a respiratory-tract transmissible illness since it could not "contain" any infectious droplets or aerosols.

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potential for contact transmission of disease as a result of touching mucosal membranes after touching the

contaminated surface. Some manufacturers have added antimicrobial coatings to their filtering facepiece respirators to address the possibility of the respirator filter becoming a fomite for transmission of infection. Antimicrobial coatings on N95 filters are intended to kill or inactivate the germs, viruses, or other biological agents for the prevention of disease. To date, the only research in this area that we are aware of are laboratory tests that assess the efficacy of the treatment to deactivate biologicals, the contact time needed to achieve those results, and that no hazards are introduced for the wearer due to the addition of the treatment to the respirator. As such, the "advantages" of antimicrobial coated respirators have not been proven or disproven. NIOSH does not evaluate the efficacy of the coatings as part of the respirator approval process. NIOSH requires the manufacturer to document that the FDA has made an assessment that the treatment does not introduce an inhalation hazard to the wearer.

(2) Is this N95 respirator better for reuse or extended use vs. an uncoated N95?
Each antimicrobial coating has a finite "residence" time of contact with the biological agent that must occur to provide the desired inactivation. The biological agents must be captured in the filter to meet the required contact time with the antimicrobial coatings to provide their deactivation. The Food and Drug Administration (FDA) evaluates product claims and issues clearance to advertise those capabilities for products that are determined to have demonstrated efficacy in the ability to prevent disease. Seeking FDA clearance is the responsibility of the manufacturer. The benefits in the use of coated N95s vs non-coated N95s would be dependent on the use conditions for the individual workers and the worksite.

(3) Which Healthcare Workers would best benefit from this specific respirator as it is more expensive than uncoated N95s?
The benefits in the use of coated N95s vs non-coated N95s would need to be assessed on the use conditions for the individual workers and the worksite.

Is there any specific benefit in using an N95 approved by FDA vs. those not approved by FDA. I see on this site there are 67 N95s approved by FDA and I am asking as there are so many other N95 models available, and am trying to understand what is the best way to choose which model(s) to purchase for healthcare worker use.

Thanks for any guidance you are able to provide.

I have purchased NIOSH approved N95 particulate respirators for our home care staff as a part of our respiratory protection program related to H1N1. CDC recommends the use of respiratory protection that is at least as protective as a fit tested disposable N95 respirator.

My question relates to fit testing. The instructions from the manufacturer are very simple, and include adjusting the straps on the mask and pinching the nose piece to ensure a proper fit. The OSHA website includes very complicated instructions for fit testing such as qualitative and quantitative testing.

Do I need to follow the OSHA fit testing instructions to be in compliance with CDC guidelines? Or can I follow the manufacturers instructions?

Lisa and Roland say:
When supplying respirators to employees OSHA requires that an employer implement a respiratory protection program which covers respirator selection, fit testing, medical fitness, maintenance, training, use, program evaluation,

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properly sealed on the face.

Fit testing and user seal checks serve different purposes – neither replaces the other.

It's great that there are fresh updates on how we can prevent horrible illnesses like H1N1 from spreading further. This N95, although I am not totally familiar with it, I know, will play a significant role in keeping people safe from the dangers of H1N1.

More than that, I think we should all take further precautionary measures to ensure that we are healthy overall. This would greatly increase our chances of avoiding viruses, bacteria, and other harmful toxins from making us sick.

The basic stuff is what matters. Practice proper hygiene; wash hands often, proper oral care, and others.

Many hospitals received "industrial" or "occupational" N95s from the National Strategic Stockpile. Some Infection Control personnel claim these N95s can NOT be used because they are not "fluid resistant" or FDA approved. When asked, manufacturers such as 3M, also write that these N95s can NOT be used in surgical suites.

If protected from splashes or sprays using a face shield, are there technical or performance reasons why these N95s can not be used? It would appear the only reason not to use these N95s is the technicality that they have not been FDA approved.

Surgical masks are required during surgical procedures and respirators during aerosol-generating procedures with pandemic influenza patients. If both conditions exist concurrently, then a surgical N95 (a respirator that has been certified by NIOSH and cleared by the FDA) is the recommended and appropriate choice (See https://www.osha.gov/Publications/3328-05-2007-English.html#RespiratoryProtectionCompliance for more details.)

The Interim Guidance on Infection Control Measures for 2009 H1N1 Influenza in Healthcare Settings, Including Protection of Healthcare Personnel recommends isolation precautions that incorporate the use of Standard Precautions as well as respiratory protection for healthcare personnel who are in close contact with patients with suspected or confirmed 2009 H1N1 influenza. The recommendation for at least an N95 respirator, properly selected and used, has been made to ensure respiratory protection is provided to reduce the exposure against the prospects of aerosolized particles. CDC continues to recommend the use of respiratory protection that is at least as protective as a fit-tested NIOSH-approved, disposable N95 respirator for these instances. Standard Precautions include the use of gowns along with eye protection for any activity that might generate splashes of respiratory secretions or other infectious material. A faceshield is one form of eye protection that can be used in conjunction with a NIOSH-approved N95 respirator for splash protection.

OSHA's Frequently Asked Questions on Pandemic Influenza Preparedness and Response Guidance for Healthcare Workers and Healthcare Employers notes: "If a pandemic influenza patient is coughing, any healthcare worker who needs to be within 6 feet of the infected patient is likely to encounter sprays of infectious material. Eye and face protection should be used in this situation, as well as during the performance of aerosol-generating procedures."

I am responsible for fit testing all of our employees at our Ambulance Service using the new PortaCount Pro+. Guidelines state that for an N-95 face mask, Fit Factor must be 100 or Greater. Before the PortaCount, we used to only carry Moldex Brand respirators (very limited in ability to form to face) they are preformed. Back when they used to put a bag over your

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We don't know of any research that identifies respirators that fit specific face sizes. However, there is research that suggests that half-facepiece elastomeric respirators are more likely to provide an acceptable fit factor for more wearers.

Regarding your question about quantitative fit testing, there is no requirement that fit testers use a quantitative test, although NIOSH research does indicate that a quantitative fit test is better at discerning fit. OSHA's 29 CFR 1910.134 still allows either qualitative or quantitative fit testing for respirators having an assigned protection factor of 10.

Yes, we understand a surgical N95 (NIOSH and FDA approved) is BEST and recommended for surgical procedures. However, since such surgical N95s are in short supply, many hospitals received other N95s from the government.

Please address this question directly:

If these other N95s (non-valved filtering facepiece) are protected from splashes by a face shield, then is there a reason they can not be used?

We agree that you need N95's to protect yourself from aerosol transmissible diseases, but we are reluctant to override your on-site infection control professionals in their hazard assessment that FDA cleared medical devices are required. The N95 respirators and Surgical N95 Respirators you received from the CDC Strategic National Stockpile are FDA-cleared medical devices with clearance in accordance with the Emergency Use Authorization of N95 Respirators issued by the FDA on April 27, 2009 and amended on May 1, 2009. This CDC-sponsored Emergency Use Authorizations (EUA) is currently in effect and will remain in effect through June 23, 2010, unless the declaration of emergency is terminated or the EUA is revoked sooner or the declaration of emergency is extended. The EUA applies only to respirators deployed from the Strategic National Stockpile. The EUA and associated information are listed on the CDC website. The long-term solution to satisfy both worker protection needs and the identified infection control requirements are to stock an adequate supply of Surgical N95s.

In developing countries there are also risk of fake N95 masks and even sometimes the government hands out sub standard ones.

I think if a home made alternative method could be done then this would really benefit

Thank you for your comment. The Buyer Beware section of the NIOSH Respirator Trusted-Source Information Page provides information on recently-rescinded approvals for various filtering facepiece respirators which were found to be non-conforming and examples of other products that misrepresent NIOSH approval.

Use of a NIOSH-certified N95 respirator ensures protection of healthcare workers and others who come in direct contact with patients with H1N1.

My department is due to receive enough N95 for our entire department, 6K+. Due to the large number of our officers, they will not be able to be fit tested promptly. What training can I provide to our officers that will give them enough information on how to don and remove the masks? Also, because the officers are not employed in a healthcare setting, what guidance can I provide them about putting a mask on a symptomatic patient/prisoner.

The use of respiratory protection by your workforce entails establishing a Respiratory Protection Program and

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The same guidance and precautions in the “masking” of patients in healthcare would apply for the jails and correctional facilities. The resources above provide guidance on donning and doffing respirators.

Personal Protection is the consistent factor to be considered in workplaces. Therefore safety awareness and prevention is very important in workplaces. [Company name] believes that a safe workplace environment ensures employee wellness, eliminates worker’s fear and anxiety, thus building employee confidence and bringing a positive impact on client services.

I have done a limited study looking at concentrations of oxygen and carbon dioxide inside surgical facemasks/respirators,commonly worn by healthcare workers. Testing was done using a highly accurate multigas industrial safety monitor configured for confined spaces using readily available components to access the air being breathed inside surgical facemasks approved by NIOSH and the FDA for consumer use. Testing was done in a “talking” and “nontalking” environment to simulate workplace environments.

Conclusions were based on published OSHA and CDC standards.

My findings show a very consistent and repeatable problem with facemask oxygen and carbon dioxide levels for the wearer……oxygen levels consistently below 19.5% oxygen and carbon dioxide levels consistently above 30,000ppm. “Talking” levels of oxygen were in the 17% range and the “Talking” levels of carbon dioxide were 40,000ppm range.”Nontalking” levels of carbon dioxide were in the 35,000ppm range.”Nontalking” oxygen levels were in the 17%-18% range. This was consistent with FDA consumer facemasks and NIOSH approved N-95 surgical facemasks. The datalog files of the gas monitor showed consistent and repeatable unacceptable air within the confined space of a surgical facemask based on current published OSHA and CDC breathing air standards.

More research is definitely needed. Awarenes of the problem is definitely needed. I would suggest “Impairment” standards with levels of impairment with gas(oxygen/carbon dioxide) exposure times figured into the equation are definitely needed. Long term medical effects of these gas exposures are definitely needed.

I am a healthcare worker and would like some answers for myself and all the other healthcare workers, consumers,firefighters,military that wear facemasks. A better product would be nice also….one that meets safe air standards!

NIOSH approval requirements for respirator types including self-contained breathing apparatus (SCBA), CBRN air-purifying respirators (CBRN APR) and CBRN air-purifying escape respirators (CBRN APER) include a maximum average concentration of inspired CO2 in accordance with prescribed test procedures.

In addition, two recently published peer-reviewed (the process by which the scientific community validates the science and methods used in specific research) journal articles and a third peer-reviewed journal article “in press” describe NIOSH research involving the measurement of CO2 and O2 concentrations in the facepiece of various respirator facepieces. While the measured O2 concentrations were reduced and CO2 concentrations were increased compared to normal atmospheric levels, they were not at the levels reported by Dr. Keller. The 3 peer-reviewed journal articles are:

1.Roberge RJ, Coca A, Williams WJ, Powell JB, Palmiero AJ: Reusable elastomeric air-purifying respirators: Physiological impact on health care workers. American Journal of Infection Control Feb 26, 2010 (Epub ahead of print)

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surgical facemasks. It should also be noted that the multigas monitor is configured for confined space testing and was

calibrated and bump tested on the day of testing.

Testing was done over a 10-15minute period. One half of the testing was done “non-talking” and one half done “talking”.

Thank you for the suggested peer reviewed articles 4-16-10. I looked up, Roberge,RJ the Surgical mask placement over N95 filtering facepiece…physiological effects on healthcare workers Respirology March 2010 and it says “respirator dead space oxygen and carbon dioxide levels were NOT harmonious with OSHA workplace ambient atmosphere standards”. My research shows the same problem! My instrumentation shows the actual gas environment inside the facemasks over time and I stand by the results which shows very substandard breathing air for wearers of facemasks. Thank you for the encouragement to get this material published. I am trying to do just that. In the meantime it would be nice for NIOSH/NPPTL, or other researchers to duplicate my results as it appears facemasks do not meet safe air breathing standards as published by CDC/NIOSH/NPPTL and OSHA.

Thanks again for allowing me to post this important issue on your blog site. I am simply a healthcare worker concerned about the workplace air I breath every day wearing a surgical facemask, along with all the other workers that do the same.

The state of California has taken this one step further. As of September 2010 it will be required that all personnel use PAPRs when performing high risk tasks on infectious patients. See CCR 5199

> Effective September 1, 2010, the employer shall provide a powered air purifying respirator (PAPR) with a High Efficiency Particulate Air (HEPA) filter(s), or a respirator providing equivalent or greater protection, to employees who perform high hazard procedures on AirID cases or suspected cases and to employees who perform high hazard procedures on cadavers potentially infected with ATPs, unless the employer determines that this use would interfere with the successful performance of the required task or tasks. This determination shall be documented in accordance with the ATD Plan and shall be reviewed by the employer and employees at least annually in accordance with subsection (d)(3).
>
> EXCEPTION 1 to subsection (g)(3)(B): Where a high hazard procedure is performed by placing the patient in a booth, hood or other ventilated enclosure that effectively contains and removes the aerosols resulting from the procedure, and the employee remains outside of the enclosure, the employee may use a respirator meeting the requirements of subsection (g)(3)(A).
>
> EXCEPTION 2 to subsection (g)(3)(B): Paramedics and other emergency medical personnel in field operations may use a P100 respirator in lieu of a PAPR.

With so many people questioning the validity of an N95 it appears that a PAPR and a P100 would certainly be excessive. Is anyone currently challenging this regulation?

We are not aware of any challenges to this regulation. Please contact Cal/OSHA directly for information and

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providing.

There is much discussion about whether surgical masks provide healthcare worker protection, but there are no studies that demonstrate they are effective at their original purpose—preventing surgical wound infections. If they don't prevent the release of particles in an outward direction, they will not prevent the penetration of particles in an inward direction. See the presentation I made at the August 2009 IOM meeting on this topic.

With respect to healthcare worker protection, there was information presented at the IOM meeting on June, 3, 2010, Current Research Issues—Personal Protective Equipment for Healthcare Workers to Prevent Transmission of Pandemic Influenza and Other Viral Respiratory Infections about a Canadian study by Loeb that is thought to demonstrate no difference between masks and surgical masks, but this study has several important flaws. The VA has been planning a clinical comparison study for more than three years (Project BREATHE), which was also discussed at the IOM meeting, but it is not clear whether this study will take place in the near future.

There are many hurdles for such studies, the most important of which involves ensuring that people wear their assigned mask throughout the workday—not just when they think they will be exposed. The study must include regular observations of facepiece wear. A good study would also measure the level of exposure encountered by each subject—by counting the number of patient contacts, identifying the infectious status of each patient contacted, and noting the amount of time spent and tasks performed during each contact. This would ensure that exposures for both groups (surgical masks and respirators) were similar—otherwise, different rates of disease could be due to different levels of exposure. Additionally, respirators must be fit tested and subjects must trained in proper donning techniques.

Regarding antimicrobial treatments, at the IOM meeting on June 3rd I presented a review of studies evaluating the effectiveness of antimicrobial filter treatments: Update on Respirators and Surgical Masks Review of Literature (2007-2010). Unfortunately, most of these studies have some significant flaws that make it impossible to conclude anything about the treatment. It is unlikely that an antimicrobial treatment will have any effect on particles penetrating a filter, because the residence time of particles is on the order of milliseconds.

Are there good N95 respirators that fit children?

In short, no. N95 respirators are not designed or intended for use by children. Respirators are generally only worn in the context of a respiratory protection program, which must be instituted and managed by the company employing the respirator users. The use of any respirator causes a physiological burden on the wearer, and this is especially a concern with children. As much as possible, children should be removed from any situation with potentially hazardous exposures, rather than attempted to be fitted with a respirator.

Are there any studies that indicate that an N100 or a P100 rspirator is more efficient than the other in filtering microbial and viral particulates from air that is not contaminated with oil? Do the different test methods and certification criteria for N100 and P100 respirators provide a basis for such a conclusion?

I am unaware of any published studies that compared the filtering efficiencies of N100 filter respirators to P100 filter respirators. The different test methods and certification criteria for N100 and P100 respirators do not provide a basis for concluding that either an N100 or a P100 filter respirator is more efficient than the other in filtering microbial and viral particulates from air that is not contaminated with oil. The particle size distributions of the sodium chloride test aerosol for the N-series filters (with a count median diameter of 0.075±0.020 micrometer and a standard geometric deviation not exceeding 1.86) and the Dioctyl Phthalate (DOP) test aerosol for the R- and P-series filters (with a count median diameter of 0.185±0.020 micrometer and a standard geometric deviation not exceeding 1.60) may appear to

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environment. It is therefore surprising to read on the net that NIOSH only recommends and do not require that each wearer undergo a fit-test.

> NIOSH agrees that the proper fit-testing and selection of an N-95 respirator is critical to ensuring that the wearer is protected.
>
> NIOSH has regulatory authority for the approval of respirators. However, NIOSH does not have regulatory authority for the use of respirators in the workplace. The Occupational Safety and Health Administration (OSHA), Mine Safety and Health Administration (MSHA), and other partner agencies have regulations governing the use of respirators in workplaces. OSHA regulations require using NIOSH approved respirators as part of a complete respiratory protection program that includes proper respirator fit-testing. Visit the OSHA web site at http://www.osha.gov and navigate to "Regulations and Standards" and find the "General Industry" standards at 29 CFR 1910.134 for full details.

I want to clarify what the recommended respiratory protection is for health care workers during a bronchoscopy and other aerosol generating or cough inducing procedure.

I understand they should wear an N-95 respirator(or PAPR) if the patient is suspected or confirmed to have an airborne transmitted disease e.g. TB, SARS, measles, chicken pox or H1N1, during these procedures.

There is some confusion among our staff as to whether the N-95 respirator should be worn by staff during all bronchoscopy procedures or aerosol generating and cough induced procedures whether or not they are suspected of an airborne trainsmitted disease.

Could you please clarify? I want to make sure our health care workers are wearing appropriate respiratory protection.

> Protection against splashes and sprays of body fluids is part of the set of standard precautions used to prevent transmission of infectious diseases from any patient. In bronchoscopy, creation of splashes and sprays of respiratory secretions is likely. Thus, when bronchoscopy is performed on a patient not suspected of having an airborne-transmitted infectious disease, the 2007 HICPAC isolation precautions guidance document recommends the use of gown and gloves, plus protection of the eyes, nose, and mouth against splashes and sprays with a face shield that fully covers the front and sides of the face, a face mask with attached shield, or a face mask and goggles. True respiratory protection to prevent inhalation of small airborne particles is indicated when performing bronchoscopy on patients suspected of having potentially airborne-transmitted infectious diseases such as those listed in the question. To minimize unnecessary exposures of healthcare workers, those performing bronchoscopies should employ respiratory protection at least at the level of a fitted N95 respirator whenever an airborne-transmitted infectious disease is considered a diagnostic possibility, even if an unlikely one.

I appreciate your response regarding recommended respiratory protection during bronchoscopies.

I was also questionning whether an N-95 respirator should be worn during all aerosolized and cough-inducing procedures, even if they are not suspected of an airborne-transmitted disease.

> Recommendations for use of PPE during other aerosol-generating procedures would parallel those for bronchoscopy. Respiratory protection at least at the level of a fitted N95 respirator should be used whenever a potentially airborne-transmitted infectious disease is a diagnostic possibility, even if an unlikely one. Some might choose to use respiratory

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A major precept of NIOSH respirator certification regulations is that approvals can only be issued to the respirator manufacturer (i.e., the entity that manufactures the device). Based on the terminology in your comment, neither you nor the investor you're representing would appear to qualify as a manufacturer of the surgical mask you are wanting to distribute. More information on the NIOSH Certification Program for Respirator Manufacturers can be found on the NIOSH website. You will want to download part 84 (second-to-last bullet) and the application procedures (second pdf file) for a better understanding of the program and the regulations that govern it. The best way to get the proper answers to your particular situation is to gain a little familiarity with the certification requirements and procedures, and talk with representatives within that program. You should read the applications procedure package after downloading. After reading, you may contact the Respirator Certification Program at (412) 386-4000 to discuss with program personnel any questions you have. However, please remember that you will not qualify to receive a "manufacturer's package," since your inquiry indicates you do not meet the regulatory definition of an applicant for approval of these devices.

Your inquiry states that the devices you are interested in distributing are surgical masks. You should be aware that surgical masks are classified as medical devices, and their distribution in the U.S. is regulated by the U.S. Food and Drug Administration (FDA). Therefore, we recommend you refer to the information on obtaining marketing clearance from the FDA's Center for Devices and Radiological Health (CDRH). This web site includes contact information for further information from the CDRH.

The new CDC guidelines say that healthcare professionals should follow droplet precautions with suspected or confirmed influenza patients. This means wearing a facemask when entering a patient's room. Alternative forms of protection that protect the face and mouth from splashes (e.g. respirators) can be used. The guidelines also state that healthcare professionals should wear respiratory protection equivalent to a fitted N95 filtering facepiece respirator or equivalent N95 respirator (e.g. PAPR, elastomeric respirator) during aerosol generating procedures (see the guidelines for more details on aerosol generating procedures). Respirators must be worn in the context of a full respiratory protection program.

We recommend that you contact your local OSHA office for further guidance about respiratory protection for the 2010-11 seasonal influenza exposures.

Barrier devices are extremely important. I teach CPR classes in Tampa, and we stress the need to always observe universal precautions. This means that whether or not a patient is infected, you treat them as if they are.

Various issues regarding N95 masks were highlighted in this column and all in all I found it to be very interesting ! My question is, is there any clause/Act in the OSHA which states that all HCWs nursing patients with PTB(pulmonary tuberculosis)must wear N95 masks? What about the visiting family members who wanted to visit? should they wear N95 too? Is ordinary 3-ply surgical masks adequate? Thank you

"Is there any clause/Act in the OSHA which states that all HCWs nursing patients with PTB(pulmonary tuberculosis)must wear N95 masks?"

OSHA has issued a Compliance Directive for Tb dated February 9, 1996. Paragraph K. Citation Policy includes the requirement for the use of respirators (29 CFR 1910.134) whenever employees may be subject to occupational exposure to Tb. Paragraph L. Violations. 2.Respiratory Protection – 29 CFR 1910.134(a)(2) and (b) provides guidance for issuing citations when non-compliance with the respiratory protection standard is determined

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to be adequate under the facility's infection control program. For your reference, we are providing some selected

examples of CDC and Infection Control recommendation documents (with excerpted text) where this issue has been addressed:

Controlling Tuberculosis in the United States. Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America. November 4, 2005 / 54(RR12);1-81

Hospitals
Hospitals should protect their patients, staff, and visitors from exposure to M. tuberculosis. The importance of effective TB infection control was emphasized during the 1985–1992 TB resurgence in the United States, when hospitals were identified as sites of transmission of multidrug-resistant TB. Implementation of effective infection-control guidelines has been effective in reducing transmission of TB in hospitals.

Roles and Responsibilities of Correctional Facilities
Correctional facilities, following requirements of the Occupational Safety and Health Administration and other regulatory agencies, should develop infection-control programs to protect inhabitants, detainees, staff, and visitors from exposure to TB. Correctional facilities should continually evaluate the effectiveness of the institutional TB-control program to eliminate transmission within the facility.

Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005 (CDC)

Respiratory Protection
Indications for Use
Respiratory protection should be used by the following persons:
• all persons, including HCWs and visitors, entering rooms in which patients with suspected or confirmed infectious TB disease are being isolated;

Airborne Infection Isolation (AII) Room Practices
Airborne Infection Isolation (AII) rooms should be single-patient rooms in which environmental factors and entry of visitors and HCWs are controlled to minimize the transmission of M. tuberculosis. All HCWs who enter an AII room should wear at least N95 disposable respirators (see Respiratory Protection). Visitors may be offered respiratory protection (i.e., N95) and should be instructed by HCWs on the use of the respirator before entering an AII room. AII rooms have specific requirements for controlled ventilation, negative pressure, and air filtration (see Environmental Controls). Each inpatient AII room should have a private bathroom, controlled ventilation, negative pressure, and air filtration (see Environmental Controls).

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (HICPAC)

II.N.3.b. Use of barrier precautions by visitors The use of gowns, gloves, or masks by visitors in healthcare settings has not been addressed specifically in the scientific literature. Some studies included the use of gowns and gloves by visitors in the control of MDRO's, but did not perform a separate analysis to determine whether their use by visitors had a measurable impact 893-895. Family members or visitors who are providing care or having very close patient contact (e.g., feeding, holding) may have contact with other patients and could contribute to transmission if barrier precautions are not used correctly. Specific recommendations may vary by facility or by unit and should be determined

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So, if we offer an N-95 mask to a visitor or family member, do they require fit testing and the medical questionaire prior to wearing the mask?

NIOSH and OSHA authorities do not apply to visitors and family members, so no medical questionnaire or fit-test is required by occupational safety and health regulations. The policies related to visitors and family member protections are generally set by the infection control (IC) practices and policies established by the IC experts at the facility. See our reply to Comment 58 for a more detailed answer.

I just started in a new facility and noticed they didn't have PAPRs for performing the sputum inductions on TB or suspected TB patients. When I asked I was told that the regulation states it can be an N-95 mask or PAPR so they have continued to use the masks. Wasn't the regulation that took affect last year state that a PAPR should be used for high hazardous procedures?

Thank you for your comment. We think you are referring to [§5199(g)(3)(B)] of the California regulation for aerosol transmissible diseases (ATDs) that was passed in 2009 and was supposed to become effective last year. You should contact CAL/OSHA regarding the implementation of this regulation.

I think i'd prefer to use Surgical N95 respirators as it give you the protection of both an N95 respirator and a surgical or procedure mask.

What studies have been done on the effects of long term surgical and N95 mask use. For healthcare providers whom wear them continously for hours and hours (sometimes up to 12), rebreathing of exhaled CO2, increased repspritory rate during stressful events, and for employeers whom require manditory masks for staff whom allergic to vaccination, what kind of safty measures should be required to give healthcare providers safty.

NIOSH is not aware of any long term studies that have been published, other than Radonovich's article in JAMA [1] that included wear for up to 8 hours. However, they analyzed tolerance only, not physiological effects. NIOSH has published data on the physiological responses of 1 hour of N95 filtering facepiece respirator use for subjects treadmill exercising at low/moderate work rates [2-4]. These studies found that in healthy healthcare workers, FFR did not impose any important physiological burden during 1 hour of use, at realistic clinical work rates, but the FFR dead-space carbon dioxide and oxygen levels were significantly above and below, respectively, the ambient workplace standards, and elevated transcutaneous CO2 is a possibility. Oxygen saturation was not compromised by the use of an N95 filtering facepiece respirator or elastomeric air-purifying respirator [5]. The presence of an exhalation valve did not significantly ameliorate the FFR's impact on transcutaneous CO2 and did not decrease respirator deadspace humidity levels. For workers who cannot be vaccinated, the usual protective measures (administrative controls, engineering controls, and personal protective equipment) should be employed.

1. Radonovich LJ Jr., Cheng J, Shenal BV, Hodgson M, Bender BS. Respirator tolerance in health care workers. JAMA 2009;301(1):36-38.
2. Roberge RJ, Coca A, Williams WJ, Powell JB, Palmiero AJ. Physiological impact of the N95 filtering facepiece respirator on healthcare workers. Resp Care 2010; 55(5):569-577.
3. Roberge RJ, Coca A, Williams WJ, Palmiero AJ, Powell JB. Surgical mask placement over N95 filtering facepiece respirators: Physiological effects on healthcare workers. Respirology 2010;15:516-521.
4. Roberge RJ, Coca A, Williams WJ, Powell JB, Palmiero AJ. Reusuable elastomeric air-purifying respirators: Physiological impact on health care workers. Am J Infect Control 2010;38:381-386.

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redonned.

America's hospitals and the US government rely almost completely on foreign made surgical masks, though competitively priced US-made masks are available. I'm curious as to why the federal government doesn't prefer US made pandemic countermeasures in the interest of national security. As a result, US hospitals are comfortable in their reliance on foreign surgical masks. Their comfort will soon entice them to become reliant on foreign made N95s, as well. If this trend continues – and it shows no signs of stopping – during future pandemics, Americans will rely on the mercy of Chinese health officials for respiratory protection – health officials who are charged with protecting the citizens of China, not the United States. Please comment.

Our Resp. Protection-Medical Clearance Evaluation Questionnaire has the question "Time of respirator use per day in hours". I cannot find any information stating how many hours per day an employee can use a respirator. Are there any documented guidelines for hospital employee use? Is there an updated employee questionnaire we should be using?

Is data available which would answer the question in order to protect oneself from common respiratory viruses in an outpatient clinical setting is an N95 mask sufficient or would
an N100 level mask be necessary?

And are there good data supporting changing masks between patients with common viral infections? Is the answer dependent upon time of interaction?

The collection efficiency of an N95 filter should be adequate for all particle sizes encountered in healthcare settings. There is no need to use a respirator with an N99 or N100 filter. The latter will have greater breathing resistance and may be more uncomfortable to wear. However, to ensure leakage between the respirator seal and the face is not excessive, it is important to use a respirator that has been properly fit tested, regardless of the filter efficiency.

If the outside of the mask has been contaminated by coming in contact with patient secretions, discard and use a new mask. In removing a contaminated mask, the risk of contact transmission will be minimized if HCWs perform hand hygiene every time before and after touching the respirator or carefully remove the respirator while wearing gloves, which should be discarded afterward. If the mask has not been contaminated, damaged or soiled, you should be able to re-donn the mask if the facility's infection control policy allows this.

Do recommendations exist for – or against – the use of surgical masks for preventing transmission of respiratory illnesses (including influenza and pertussis) in K-12 schools?

If so, what are they and what is the evidence behind them?

We have been asked by our local school district to share some of our H1N1-era surgical masks. Sharing might seem well intentioned, but we are concerned that doing so would send the message that our health district recommends their use. We are not convinced that that should be our message.

Answers to questions like #69 above are, I am confident, technically correct, but they do not address the practical issue of having to determine in which situations public health representatives should recommend mask or respirator use.

Thank you for this blog.

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non-pharmaceutical interventions by adults and children showed that respondents were in support of basic hygiene practices (e.g. covering coughs, washing hands, using hand sanitizer) but were not in support of using masks or gloves (Stebbins et al, 2009). Given these results, an intervention with training in hand and respiratory hygiene and encouragement to use hand sanitizer in 5 elementary schools (compared to 5 control schools) showed significantly fewer confirmed influenza A infections (52%) and 26% fewer absences, but no effect on lab confirmed influenza B infections (Stebbins et al, 2011).

The gathering efficiency of an N95 filter should be satisfying ample for all particle sizes encountered in healthcare settings. There is no dependence to use a respirator later than an N99 or N100 filter. The latter will have greater animate resistance and may be more uncomfortable to wear. However, to ensure leakage together in the midst of the respirator seal and the slope is not excessive, it is important to use a respirator that has been properly fit tested, regardless of the filter efficiency.

Health and safety in the workplace is very important and something which is often taken for granted. Making sure there is a proper policy in place in vital to build employees confidence. At times they may fear dangerous health hazards occurring without a correct policy or personal protection which may affect their work.

Thanks for the article. Recall reading about Practical issues such as compliance and supply being part of the argument for use of surgical masks rather than N95 respirators in most clinical settings.

My office claims that no fit-test for the NIOSH-approved HY8510 respirator is required. Is this true?

All NIOSH-certified filtering facepiece respirators require fit testing. This includes an initial fit testing and training in the respirator's use and fit testing at least annually after that.

The OSHA Respiratory Protection Standard includes more details about the types of fit testing required for different types of respirators.

What are the recommendations for the storage of individual respirators that staff use for their shift after placing them in a plastic bag that is labeled with their name, date and time?

As an IH professional, I can attest to the difference in the fit and quality of effectiveness between surgical masks and N95 filtering facepieces. The technology is fantastic and I enjoy inspecting the research that is available.

However, I am in strong disagreement with the aspect of requiring actual qualitative fit testing for each healthcare worker wearing N95 PPE. The actual 'fitting' of the mask is, in my opinion the least effective aspect of a respiratory program that deals with N95's.

In the United States employers are required by OSHA to conduct annual respirator fit testing for every employee required to wear a respirator as part of their job. They may use either quantitative or qualitative fit testing for half-mask air purifying respirators such as N95 filtering facepiece respirators. Without a fit test, it is impossible to know whether a particular manufacturer, model and size will fit a particular person. Past NIOSH research (see citation below) has shown that a fit test is a very important feature of a respiratory protection program.
Coffey CC, Lawrence RB, Campbell DL, Zhuang Z, Calvert CA, Jensen PA. [2004] Fitting Characteristics of Eighteen N95 Filtering-Facepiece Respirators. J Occup Environ Hyg 1:262-371.

very nice post, i certainly love this website, keep on it

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Thanks

The hospital where I work has been doing FIT-testing for every employee since the implementation of the 2009 interim guidelines. This was done in order to be in compliant with the CDC guideline and OSHA standards. I am trying to reexamine our current policy. I am writing to you to confirm that a hospital is required to do annual FIT-testing only on employees who need to wear N95 Respirators for their job.Please confirm or correct my interpretation if this guideline. Thank you for your guidance in this matter.

Some hospitals elect to fit test and train all staff, while others select a subset of staff (e.g., , one strategy could be to include only staff who work in areas that have airborne isolation rooms as well as all respiratory therapists)

Under OSHA's 1910.134 respiratory protection standard, a hazard assessment should be performed first to determine which employees should be in the employer's respiratory protection program. A variety of strategies exist for performing a hazard assessment and selecting which workers need to wear a respirator on the job. NIOSH collaborated on two recently published documents (1,2) that provide best practices and resources to help hospitals develop and implement an effective respiratory protection program, with an emphasis on preventing transmission of aerosol transmitted diseases.

Please consult these reports for additional details.

For those employees that must be fit tested, the fit testing should be done initially (before the employee is required to wear the respirator in the workplace) and must be repeated at least annually. Fit testing must also be conducted whenever respirator design or facial changes occur that could affect the proper fit of the respirator.

1. https://www.osha.gov/Publications/OSHA3767.pdf

2. http://www.jointcommission.org/assets/1/18/Implementing_Hospital_RPP_2-19-15.pdf

Surgical masks are not designed for use as particulate respirators and do not provide as much respiratory protection as an N95 respirator. Surgical masks provide barrier protection against droplets including large respiratory particles...

Hi.

I would like to clarify one issue.

During haze in ASEAN few weeks ago, there was rumor on The correct use of 3lpy mask in order to prevent direct inhalation of the haze particles. They mentioned about wearing the 3ply mask in opposite way with this argument :

a. on normal occasion, the 3ply mask prevent the contaminant from the weare from being released the environment.

b. while during haze, in order to prevent the haze particles contaminate the wearer's respiratory tract, the mask should be worn opposite way (inside layer outside, and vice versa)

Is it true?

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http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/RespSource.html
This page provides information to understand the types of respirators, how to identify approved models and outlets for purchase, a listing of all NIOSH-approved and FDA-cleared surgical N95 respirators, a listing of recently revoked respirator approvals and relevant User Notices.

Hello,
I am doing my project on air pollution recently, I just have few questions want to ask, and I will be so happy if you would like to reply me.
1. Expect respirators, is there anyway else to minimise the amount of pollutants that we breath in?
2. Is it right that stay outdoor would reduce the effect of air pollution, as the ventilation is better outside, and air is fresher?
3. Would people experience more serious injury if they wear the masks all times then take it off, rather than don't wear any masks/respirators?
This essay have helped me a lot in my project, and please reply me if possible, thank you.

We have some N95 masks in storage. Is there an expiration date or any guidance on using N95 masks that have been properly stored for 6 years?

NIOSH-approved N95 respirators are not required to have an expiration date. Some manufacturers specify an expiration date in the user instructions. You should not use respirators past an expiration date provided by the manufacturer. If the respirator does not have an expiration date, you may seek guidance from the manufacturer on whether time and storage conditions have an effect on the respirator's performance.

Great read.
I was searching for the guide/ detailed information about "How are surgical masks and respirator filters" nowhere my search ends.
Really it is a great guide about N95 masks.
I have purchased this n95 mask online. n95 mask how long can be used? This comes with 1 filter, I also wanted to know that for which frequency I have to change my filter?

There is no specific maximum time of use of an N95 FFR. Unless the manufacturer identifies a specified duration of use, for example "single use only", the service life of all filters is limited by considerations of hygiene, damage, and breathing resistance. All filters should be replaced whenever they are damaged, soiled, or causing noticeably increased breathing resistance. Follow the manufacturer's recommendations for specific information on the model you are using.

I found this blog is interesting ..I read entire blog very new to me....

This is indeed a very interesting article. My question is whether the difference in performance between the two masks has also been studied for larger particles? Are there still differences for cotton dust?

We were unable to find any studies that directly compare respirator and surgical mask performance for larger particles (> 1 micrometers). There are many studies on particles smaller than this range.

The performance of NIOSH-approved respirators larger than one micron has been studied. Those studies show that almost all of the particles above 5 micrometers are collected in the respirator filter. Loose fitting surgical masks do not provide the same level of protection as NIOSH certified respirators because they do not seal tightly to the face. NIOSH-

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Is there any fit test requirements for the NIOSH & FDA approved N95 respirator?

Does manufacturer need to perform fit test for their N95 product before launching to the market?
If there is no fit test data from the approved N95 respirator, then how can we choose a proper N95 mask with respect to the leakage aspect?

Thank you.

1.) Yes, fit testing is required for tight-fitting respirators before use in the workplace, including surgical N95 respirators that are NIOSH-approved and cleared by the FDA. A “fit test” tests the seal between the respirator’s facepiece and the wearer’s face. It takes about fifteen to twenty minutes to complete and is performed at least annually. After passing a fit test with a respirator, the employee must use the exact same make, model, style, and size respirator on the job.

2.) No. Fit testing is the responsibility of the mask wearer’s employer, not the respirator manufacturer. Proper fit is individual-specific for the wearer, assessing the masks ability to seal with that wearer’s face, and not a general property of the mask. Manufacturers provide guidance about fit testing in their user instructions.

3.) Employers should offer a variety of makes, models, and sizes for fit testing. The ability of any given mask varies because of the facial sizes of workers and the respirator models and sizes. If a respirator fails the fit test, then another make, model, style, or size must be tried until one is found that fits the employee properly. Experience gained during initial fit testing will guide you for future selection of proper N95 masks.

This is all very informative. I have a question about the shelf life of masks. It makes sense that N95 masks have expiration dates but does those typical surgical masks have limited shelf life too?

Thanks!

NIOSH does not evaluate or approve surgical masks. We suggest you contact the US Food & Drug Administration (FDA) https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/masks-and-n95-respirators

FDA Info line: 1-888-INFO-FDA (1-888-463-6332)

How should we wear mask which has 2 colors (which side does the colored area must be) and what if the mask has no color at all just plain white. Please enlighten as some sources are saying colored part of the surgical mask must face outwards and the white one inwards.

It depends on the model of surgical mask being referenced. Typically, the blue or colored side of the mask faces outward, while the white side faces inward towards the mouth. However, you should refer to the surgical mask’s user instructions to verify donning instructions.

Can you use a industrial mask (P100) to protect against the new Coronavirus? I got a [product name removed], wondering now if I wasted my time.

At this time, CDC is not recommending the use of face masks among the general public for the novel coronavirus. For the general American public, who are unlikely to be exposed to this virus, the immediate health risk from 2019-nCoV is considered low at this time. When properly fitted and worn, N95 respirators filter out at least 95% of airborne particles including large and small particles. Since airborne biological agents such as bacteria or viruses are particles, they can be filtered by particulate respirators. We cannot recommend a specific manufacturer of respirators, however, please

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2. Even when N95 respirator reuse is practiced or recommended, restrictions are in place which limit the number of times the same respirator is reused. Thus, N95 respirator reuse is often referred to as "limited reuse." To maintain the integrity of the respirator, it is important for HCP to hang used respirators in a designated storage area or keep them in a clean, breathable container such as a paper bag between uses. It is prohibited to modify the N95 respirator by placing any material within the respirator or over the respirator. Modification may negatively affect the performance of the respirator and could void the NIOSH approval. (https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-supply-strategies.html)

The use of a surgical mask over an N95 has the high potential to adversely affect the fit of the respirator. Healthcare staff have not been fit tested with a surgical mask over the N95 and as such, the fit of the respirator under these conditions will not have been verified. Is there sufficient data that suggests this is a safe practice?

Your input and assistance is appreciated. Thank you!

> Thank you for bringing this issue to our attention. You are correct that the use of a surgical mask over an N95 respirator may negatively affect the performance of the respirator. The use of a surgical mask over an approved N95 respirator would void the NIOSH Approval as it is a configuration of the respirator that was not evaluated or approved. Our recommendation would be to use an N95 with appropriate eye or face protection which do not interfere with the fit of the respirator. Additionally, this recommendation is consistent with the fit test requirements of the OSHA Respiratory Protection Standard where they require fit testing of the NIOSH-approved respirator. We will revise the language on our Pandemic Extended Use and Limited Reuse Guidance webpage to avoid any further confusion.

Given the fact that N95 masks have all but disappeared from shelves across the country as a result of the threat posed by the Wuhan coronavirus, the comment of Mike Bowen on April 9, 2012, concerning the unfortunate dependence of this country on foreign made masks seems, unfortunately, to have been spot on. Nothing apparently changed in the interim, and now it is likely to be a very long time before China begins shipping N95 masks to the US.

"Desperate times, desperate measures." As laymen, like myself, begin efforts to make their finite supply of N95 masks stretch as far as possible, I am hoping to obtain answers to the following questions:

1. Will placing an N95 mask in an oven at low temperature in order to sterilize it actually work?

2. If the answer to No. 1 is in the affirmative, will doing so damage the mask's future effectiveness? (Damage to the mask's material and any coatings involved is a concern.)

3. If the answer to No. 1 is in the affirmative, what oven temperature would be appropriate?

4. Will placing a potentially contaminated mask in the direct rays of the sun sterilize the mask without harming it?

5. The answer to No. 4 is negative, for how long should the mask remain in the sunlight, and how many times can the process be expected to be used safely? (Possible UV damage is a concern.)

6. Paint respirators that are rated P95 use replaceable filters. Given that these filters are meant for use over substantial periods for industrial use, can they likewise be used for virus protection for protracted periods of time?

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10. If the answer to No. 9 is in the affirmative (i.e., there is a concern about the prior use of the filters), should the user

have any concerns about using sealed and unissued filters for the gas masks, even if they were manufactured quite some time ago?

11. It is my understanding that standard surgical mask material is inferior to the N95 mask material. An N95 mask's material is said to stop droplets larger than 3 microns from passing through it. What size microns will the surgical mask's material stop?

14. What is the likely impact of using tape to seal the edges of a standard surgical mask to the face in an effort to make it more effective? While doing so would force all air to pass directly through the mask while breathing, would the increase of moisture on the mask offset any benefits to the user?

Thank you for your inquiry. At this time, CDC is not recommending the use of face masks or respirators among the general public for COVID-19. For additional details, please find more information in our blog about non-occupational respirator use: http://blogs.cdc.gov/niosh-science-blog/2018/01/04/respirators-public-use. When properly fitted and worn, N95 respirators filter out at least 95% of airborne particles including large and small particles. Since airborne biological agents such as bacteria or viruses are particles, they can be filtered by particulate respirators.

There are significant differences between face masks, N95 filtering facepiece respirators, and elastomeric respirators for you to consider. Our infographic provides a comparison between face masks and these respirator types: https://www.cdc.gov/niosh/npptl/pdfs/UnderstandingDifference3-508.pdf.

Many of the activities you have described are not recommended disinfection techniques for respirators. Please consult the manufacturer's instructions on how to clean a reusable respirator.

If your concern is having sufficient supply of N95 respirators for industrial use (i.e., not against infectious diseases), NIOSH has issued a factsheet on extended use and limited reuse of N95 filtering facepiece respirators: https://www.cdc.gov/niosh/docs/2018-128/pdfs/2018-128.pdf?id=10.26616/NIOSHPUB2018128. Within this fact sheet, there is a link to specific pandemic planning guidance for extended use and limited reuse of N95 filtering facepiece respirators in healthcare settings: https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html#risksextended.

Unless the manufacturer identifies a specified duration of use, the service life of filters is limited by considerations of particulates clogging the filter which decrease the airflow below minimum acceptable levels, unacceptable contamination/soiling, or physical damage. All filters should be replaced whenever they are damaged, soiled, or causing noticeably increased resistance which results in decreased airflow. Follow manufacturer's recommendations for specific information on the model you are using.

Finally, please keep in mind that any changes to a respirator that modifies the design documented in the NIOSH approval records (including heat-treating, sanitizing with chemicals, or performing UV or solar irradiation) would void the NIOSH approval.

That's all well and good CDC, but where are the N95 masks? No one has them in stock at the stores. Its highly likely the vast majority of people have no n95 masks in their houses. Are you going to wait until this has infected a large number of people before you fix the n95 supply issues? What have you been doing over the past decades when you were telling us

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/coronavirus/2019-ncov/php/preparing-communities.html.

I have noticed that the clearance of the FDA is about the fluid and flame resistance. Does this mean the N95 without the FDA clearance are not good at fluid and flame resistance? Besides, what about the “industrial” N95? Where can I get the detailed standard of the classification (like PDF files)?

Why is my company (a multi-national publicly traded and world recognized manufacturer) recommending to wear N95 masks to their employees in China while health officials in the US are recommending that American’s should not wear N95 masks? Are the Chinese masks better? Is the difference in recommendation dependent upon the availability of the masks in the respective countries? Who should I trust, my employer, or my government?

Due to the nature of your inquiry and it’s relation to Coronavirus Disease 2019 (COVID-19), please visit CDC’s COVID-19 website where you can find the most up-to-date information on the outbreak and get the latest answers to frequently asked questions. You can also contact CDC-INFO or by calling 800-232-4636.

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